

fermentation as recited in new claims 36 and 55, nor does the originally filed disclosure explicitly refer to a starting stage phosphorus concentration. Moreover, nowhere does the disclosure as originally filed clearly provide for an initial concentration of 0.15% w/v at the starting stage followed by a narrower concentration range of 0.0015% to 0.15% w/v as recited in claim 36. Rather, the disclosure as originally filed provides only that an initial concentration of phosphorus is provided which does not exceed a specific amount during the growth phase, and that the phosphorus concentration is preferably allowed to approach zero by the fortieth hour of the fermentation. See specification, first full paragraph of page 2 to first full paragraph of page 3."

Applicants respectfully disagree.

"To comply with the written description requirement of 35 USC 112, ¶1, ..., each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim 'is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.' *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998)" [MPEP 2163 II.3.(b), page 2100-165]; and MPEP 2163.02 notes (at page 2100-167) "The subject matter of the claim need not be described literally (i.e. using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement."

Claim 36 as presently filed requires that at the starting stage of fermentation the concentration of phosphorus be less than 0.15% w/v; and that during the growth phase of the fermentation it be maintained between 0.0015% and 0.15%. Claim 55 as filed requires only that after the starting stage of fermentation and during a growth phase of the fermentation the concentration of phosphorus be maintained between 0.0015% and 0.15%.

Applicants concede that the specification does not explicitly refer to the phosphorus concentration at a starting stage of fermentation. However, it is known from the specification that clavulanic acid is prepared by fermentation, that the fermentation includes two phases, a growth phase in which biomass is produced and a stationary phase during which growth does not occur but secondary metabolites such as antibiotics are generally produced. See the discussion near the bottom of page 1 of the specification. Thus it is known that clavulanic acid-producing organisms when fermented for the production of clavulanic acid undergo a two-stage fermentation, a first, growth, stage where the organism multiplies, and a second, production, stage, where the clavulanic acid is produced. It is also evident that any fermentation must have a starting stage, by which is meant no more than the stage or point at which the fermentation begins: this is not a requirement of the science of fermentation, it is simply a matter of definition in that any activity that is not continuous must start (and therefore have a starting stage) and presumably also end (and therefore have an ending stage, though that is not relevant here).

Further, the specification clearly states that the concentration of phosphorus in the fermentation broth shall be "less than 0.15% w/v" (page 2, line 26), "preferably maintained below a limit of 0.15% w/v during the growth phase" (page 2, lines 27-28), and "is preferably 0.0015 to 0.15% w/v" (page 3, lines 2-3).

As mentioned above, it is clear that the production fermentation must include a starting stage. It is also clear that the concentration of phosphorus shall be less than 0.15% during the fermentation. Because the fermentation includes the starting stage and because the concentration of phosphorus shall be less than 0.15% during the fermentation, the concentration of phosphorus during the starting stage of fermentation must therefore be less than 0.15%. Applicants respectfully submit that there is ample implicit disclosure in the application as filed to support the limitation that the phosphorus concentration shall be less than 0.15% at the starting stage of fermentation. Withdrawal of the rejection as to this limitation is respectfully requested.

Applicants note that the limitation is merely that the concentration shall be "less than 0.15%", not that it shall be "0.15%", as suggested in the Final Rejection at page 3, line 6.


With regard to the requirement in claims 36 and 55 that the concentration of phosphorus shall be maintained between 0.0015 and 0.15% during the growth phase, as required by claims 36 and 55, Applicants point to page 2, lines 27-28, of the application, where it states that "The phosphorus concentration is preferably maintained below a limit of 0.15% w/v during the growth phase"; and to page 3, lines 2-3, where it states that the phosphorus concentration is "preferably 0.0015 to 0.15%".

Applicants respectfully submit that there is ample explicit (and implicit) disclosure that the concentration of phosphorus should be maintained between 0.0015 and 0.15% during the growth phase of fermentation.

### Conclusion

For the reasons given above, Applicants respectfully submit that, contrary to the Examiner's statements, there is ample explicit and/or implicit disclosure in the application as filed to support the terms "at a starting stage of fermentation the concentration of phosphorus is less than 0.15% w/v" (claim 36, lines 5-6) and "during a growth phase of the fermentation ... to maintain the concentration of phosphorus between 0.0015% and 0.15%", so that Claims 36-55 do satisfy the written description requirement of 35 USC 112, ¶1. Withdrawal of the rejection, and allowance of the claims, are respectfully requested.

Respectfully submitted,

  
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